510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k040972

B. Purpose For Submission:

Premarket Notification 510(k) for GenChem, Inc. intentions to manufacture and market the GenChem Calcium Reagent Kit.

C. Analyte: Calcium

D. Type of Test:

Quantitative Photometric End-Point

E. Applicant: GenChem, Inc.

F. Proprietary and Established Names:

GenChem, Inc., Calcium, Azo Dye Reagent

G. Regulatory Information:

Regulation section:

1. Regulation section:

21 CFR §862.1145 - Calcium test system.

2. Classification:

Class II

3. Product Code:

CJY

4. Panel:

75 (Chemistry)

H. Intended use(s):

1. Intended use(s)

GenChem Calcium Reagent is intended for the quantitative determination of total calcium in serum, plasma and urine on the Beckman SYNCHRON CX3 System to aid in the diagnosis of diseases associated with hypercalcemia and hypocalcemia.

2. Indication(s) for use:

GenChem Calcium Reagent is intended for the quantitative determination of total calcium in serum, plasma and urine on the Beckman SYNCHRON CX3 System to aid in the diagnosis of diseases associated with hypercalcemia and hypocalcemia.

3. Special condition for use statement(s): For Prescription Use.

4. Special instrument Requirements:
Beckman SYNCHRON CX3 System

I. Device Description:

GenChem Calcium reagent is a liquid composed of Arsenazo III and buffer for the quantitative determination of Calcium in serum, plasma and urine on the Beckman Synchron CX3 System.

J. Substantial Equivalence Information:

GenChem claims substantial equivalence to the OEM Reagent marketed by Beckman and HiChem 510(k) 941764.

1. Predicate device name(s): HiChem Calcium Reagent for the CX7

2. Predicate K number(s): (k941764)

3. Comparison with Predicate:

Device Name	GenChem Calcium Reagent Kit	Predicate Device HiChem & Beckman Calcium Reagent Kit
510(k) Number	(k040972)	(k941764)
Chemical Principle	Arsenazo III	Arsenazo III
Intended Use	For the quantitative determination of calcium in serum, plasma, or urine.	For the quantitative determination of calcium in serum, plasma, or urine.

Device Name	GenChem Calcium Reagent Kit	Predicate Device HiChem & Beckman Calcium Reagent Kit
Format	Liquid, ready to use.	Liquid, ready to use.
Composition	Arsenazo III, buffer and surfactant.	Arsenazo III, buffer and surfactant.
Linearity	0-15.5 mg/dL	0-15.5 mg/dL
Storage	2-30 °C	2-30 °C

K. Standard/Guidance Document Referenced (if applicable):

Within-Day and Day-to-Day precision was determined according to NCCLS EP5-A.
Linearity was performed according to NCCLS EP6-A Guideline.
Analytical specificity Determined according to NCCLS EP7-A.

L. Test Principle:

Arsenazo III + Calcium = Calcium – Arsenazo III Complex.

Calcium in the sample reacts with arsenazo III in the buffered reagent to form a blue complex. The absorbance of the reagent is measured bi chromatically at 650 nm and 700 nm immediately before the 21 seconds after sample addition. The change in absorbance is proportional to the calcium concentration in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Control sera and diluted urine pools were each assayed 3 times per day over 10 days on a Beckman SYNCHRON CX3 System.

Precision of Total Calcium Recoveries (mg/dL)

		Within Run			Total Imprecision	
Sample	**n**	**mean**	**SD**	**%CV**	**SD**	**%CV**
Serum 1	60	7.2	0.06	0.7	0.10	1.4
Serum 2	60	10.6	0.05	0.5	0.09	0.9
Serum 3	60	14.0	0.05	0.3	0.09	0.6
Urine 1	60	4.0	0.03	0.7	0.16	4.1
Urine 2	60	12.7	0.06	0.5	0.13	1.0

b. Linearity/assay reportable range:

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards (HiChem Align) ranging from 0 to 15 mg/dL were analyzed in triplicate on the Beckman CX7 and the results analyzed by the Least Squares method. The results gave a slope of 0.911 with an intercept of 0.34, a standard error of estimate of 0.35 and $r^2 = 1.000$. Samples exceeding these limits should be diluted with normal saline and reanalyzed. Multiply the result by the appropriate dilution factor.

		Usable Range	
Specimens	Range	Conventional Units	SI Units
All	Normal	0.1 to 15 mg/dL	0.5 – 3.75 mmol/L

c. Traceability (controls, calibrators, or method):

Beckman Calibration Standards 1 and 2 for the CX3 System

d. Detection limit:

The sensitivity of this method was investigated by assaying serum first with a known concentration and then diluting the sample until the minimum result obtained and then run in replicates of 10 on the Beckman SYNCHRON CX3 System. Under the conditions described the limit of detection for this method was found to be 0.1 mg/dL.

Analyte	**Limit of Detection**
Calcium	0.1 mg/dL

e. Analytical specificity:

Determined according to NCCLS EP7-A, Hemoglobin levels up to 500 mg/dL, Bilirubin levels up to 20 mg/dL, and Lipemia levels up to 1800 mg/dL were tested and did not show any adverse effect on a stock sample with a calcium level of 9.4 mg/dL. Stock solutions of the substance to be tested were prepared at 20x concentrations and 0.5 ml of this stock was placed in a 10 ml volumetric flask and made up to volume with the base pool. The control stock was prepared similarly but with water as the diluent. Heparin, Lithium Heparin Ammonium Heparin, and EDTA are acceptable anticoagulants.

f. Assay cut-off:

Not applicable for this type of device.

2. Comparison studies:

a. Method comparison with predicate device:

Serum, plasma, and urine specimens, collected from adult patients, ranging from 0 to 15.2 mg/dL were assayed for total calcium on a Beckman SYNCHRON CX3 System using GenChem and Beckman calcium reagents. Results were compared by least squares linear regression and the following statistics were obtained.

VALUE	SERUM	PLASMA	URINE
Intercept	-0.1	-0.1	0.1
Slope	0.994	0.973	0.999
R^2 Value	0.971	0.980	0.999
N	82	84	76
Range (mg/dL)	7.0 – 10.6	7.4 – 10.5	0.4 – 15.2

b. Matrix Comparison

See above method comparison studies.

3. Clinical studies:

a. Clinical sensitivity:

Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Clinical studies are not typically submitted for this device type.

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values for total calcium are listed below. Use these ranges only as guides. Each laboratory should establish its own normal ranges.

	Normal Ranges[1.]	
Specimens	Conventional Units	SI Units
Serum/Plasma	8.4 - 10.2 mg/dL	2.10 - 2.55 mmol/L
Urine	100 - 300 mg/day	2.5 - 7.5 mmol/day

[1.] Burtis, C.A., Ashwood, E.R. (eds.). Tietz Textbook of Clinical Chemistry. W.B. Saunders Company. Philadelphia, P.A. (1994).

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.